

AMENDMENTS TO THE CLAIMS

1. (Currently amended) A rapidly disintegrating and rapidly dissolving solid oral compressed composition ~~comprising~~ consisting essentially of:
 - a. one or more magnesium salts;
 - b. ~~one or more hydrophilic polymers, wherein the one or more hydrophilic polymers is a combination of~~ the hydrophilic polymers polyethylene glycol and poloxamer;
 - c. one or more disintegrants selected from the group consisting of crospovidone, low substituted hydroxypropylcellulose, croscarmellose sodium, and sodium starch glycolate;
 - d. optionally one or more surfactants;
 - e. optionally one or more glidants;
 - f. optionally one or more fillers; and
 - g. optionally one or more lubricants;
 - h. wherein the composition provides a substantially stable dissolution profile when evaluated in vitro according to USP <711> for the one or more magnesium salts when the composition is stored for at least two months at 40°C and 75% relative humidity in a sealed container-enclosure system; and the composition excludes microcrystalline cellulose ~~and erythritol~~.
2. (Original) The composition of claim 1, wherein the magnesium salt is MgO, Mg Carbonate, MgF₂, or Mg(OH)₂.
3. Canceled.
4. Canceled.
5. Canceled.
6. (Original) The composition of claim 1 further comprising a coating surrounding the compressed composition.
7. (Original) The composition of claim 1, wherein the composition is included in a tablet or capsule dosage form
8. (Original) The composition of claim 1, wherein the composition is prepared by dry granulation.

9. (Original) The composition of claim 1, wherein the composition is prepared by direct compression.
10. (Original) The composition of claim 1, wherein the magnesium salt is a sparingly soluble, slightly soluble, very slightly soluble, practically insoluble or insoluble salt.
11. (Original) The composition of claim 1, wherein the magnesium salt is the only component present in a therapeutically effective amount.
12. (Original) The composition of claim 1 further comprising a capsule shell within which the compressed composition is enclosed.
13. (Original) The composition of claim 1, wherein the compressed composition is tablet or pill.
14. (Original) The composition of claim 13, wherein the tablet or pill exhibits a hardness of about 4 kp to about 50 kp.
15. (Original) The composition of claim 1, wherein the dissolution medium for evaluation is dilute hydrochloric acid.
16. (Original) The composition of claim 1, wherein the solid oral compressed composition is in a sealed container-enclosure system during storage.
17. (Currently amended) The composition of claim 16, wherein
 - a. the container comprises a material selected from the group consisting of glass, metal, or polymers;
 - b. the enclosure comprises a material selected from the group consisting of metal or polymers; and
 - c. the container-enclosure system is sealed by mechanical tightening and induction sealing of a ~~taper~~ tamper evident liner onto the orifice of the container.
18. (Original) The composition of claim 17, wherein
 - a. the container comprises high density polyethylene;
 - b. the enclosure comprises CRC or non-CRC polypropylene; and
 - c. the container-enclosure system is sealed using an appropriate torque and an induction sealed aluminum tamper evident liner.
19. (Original) The composition of claim 18, wherein the compressed composition is prepared by direct compression.

20. (Original) The composition of claim 1, where in the compressed composition contains less than 7.5% water.
21. (Original) The composition of claim 20, wherein the compressed composition contains less than 5.5% water.
22. (Original) The composition of claim 21, wherein the compressed composition contains less than 4% water.
23. (Currently amended) A rapidly disintegrating and rapidly dissolving solid oral dosage form ~~comprising~~ consisting essentially of:
 - a. a compressed composition comprising:
 - i. one or more magnesium salts;
 - ii. ~~one or more hydrophilic polymers, wherein the one or more hydrophilic polymers~~ is a combination of the hydrophilic polymers polyethylene glycol and poloxamer;
 - iii. one or more disintegrants selected from the group consisting of crospovidone, low substituted hydroxypropylcellulose, croscarmellose sodium, and sodium starch glycolate;
 - iv. optionally one or more surfactants;
 - v. optionally one or more glidants;
 - vi. optionally one or more fillers; and
 - vii. optionally one or more lubricants; wherein
 - viii. the composition provides a substantially stable dissolution profile when evaluated in vitro according to USP <711> for the one or more magnesium salts when the composition is stored for at least two months at 40°C and 75% relative humidity in a sealed container-enclosure system, and the composition excludes microcrystalline cellulose ~~and erythritol~~.
24. (Original) The dosage form of claim 23, wherein the magnesium salt is the only component present in a therapeutically effective amount.
25. (Original) The dosage form of claim 23, wherein the magnesium salt is a sparingly soluble, slightly soluble, very slightly soluble, practically insoluble or insoluble salt.
26. (Original) The dosage form of claim 25, wherein the magnesium salt is selected from the group consisting of MgO, Mg(OH)₂, MgF₂, and Mg Carbonate.

27. Canceled.
28. Canceled.
29. (Original) The dosage form of claim 23, wherein the composition is prepared by dry granulation.
30. (Original) The dosage form of claim 23, wherein the composition is prepared by direct compression.
31. (Original) The dosage form of claim 23, wherein the composition contains less than 7.5% water.
32. (Original) The dosage form of claim 31, wherein the composition is prepared by dry granulation.
33. (Original) The dosage form of claim 31, wherein the composition is prepared by direct compression.
34. (Original) The dosage form of claim 23 further comprising a coating surrounding the compressed composition.
35. (Original) The dosage form of claim 23 further comprising a capsule shell within which the compressed composition is enclosed.
36. (Currently amended) A rapidly disintegrating and rapidly dissolving compressed composition adapted for oral administration to a subject ~~comprising~~ consisting essentially of:
- a. one or more magnesium salts;
 - b. ~~one or more hydrophilic polymers, wherein the one or more hydrophilic polymers is a combination of~~ the hydrophilic polymers polyethylene glycol and poloxamer;
 - c. one or more disintegrants selected from the group consisting of crospovidone, low substituted hydroxypropylcellulose, croscarmellose sodium, and sodium starch glycolate;
 - d. optionally one or more surfactants;
 - e. optionally one or more glidants;
 - f. optionally one or more fillers; and
 - g. optionally one or more lubricants; wherein
 - h. the magnesium salt is the only component present in a therapeutically effective amount;

- i. the composition provides a substantially stable dissolution profile when evaluated in vitro according to USP <711> for the one or more magnesium salts when the composition is stored for at least two months at 40°C and 75% relative humidity in a sealed container-enclosure system;
 - j. the composition contains less than 7.5% water, and the composition excludes microcrystalline cellulose ~~and erythritol~~.
37. (Original) The composition of claim 36, wherein the magnesium salt is a sparingly soluble, slightly soluble, very slightly soluble, practically insoluble or insoluble salt.
38. (Original) The composition of claim 37, wherein the magnesium salt is selected from the group consisting of MgO, Mg(OH)₂, MgF₂, and Mg Carbonate.
39. (Original) The composition of claim 37, wherein the composition is prepared by direct compression or dry granulation.
40. (Original) The composition of claim 36, wherein the composition is prepared by direct compression or dry granulation.
41. (Original) The composition of claim 36, wherein the composition is prepared by a process that does not include the addition of water.
42. (Currently amended) The composition of claim 36, wherein
- a. the container comprises a material selected from the group consisting of glass, metal, or polymers;
 - b. the enclosure comprises a material selected from the group consisting of metal or polymers; and
 - c. the container-enclosure system is sealed by mechanical tightening and induction sealing of a ~~taper~~ tamper evident liner onto the orifice of the container.
43. Canceled.
44. (Currently amended) A rapidly disintegrating ~~and~~ rapidly dissolving solid oral compressed composition ~~comprising~~ consisting essentially of:
- a. one or more magnesium salts;
 - b. ~~one or more hydrophilic polymers, wherein the one or more hydrophilic polymers is a combination of~~ the hydrophilic polymers polyethylene glycol and poloxamer;

- c. one or more disintegrants selected from the group consisting of croscopovidone, low substituted hydroxypropylcellulose, croscarmellose sodium, and sodium starch glycolate; and
 - d. at least one or more of the following: surfactant, glidant, filler, and lubricant; wherein
 - e. the composition provides a substantially stable dissolution profile when evaluated in vitro according to USP <711> for the one or more magnesium salts when the composition is stored for at least two months at 40°C and 75% relative humidity in a sealed container-enclosure system;
 - f. the composition is prepared by a substantially anhydrous process;
 - g. the magnesium salt is a sparingly soluble, slightly soluble, very slightly soluble, practically insoluble or insoluble salt; and the composition excludes microcrystalline cellulose ~~and erythritol~~.
45. (Original) The composition of claim 44, wherein the magnesium salt is selected from the group consisting of MgO, Mg(OH)₂, MgF₂, and Mg Carbonate.
46. (Original) The composition of claim 44, wherein the composition is prepared by direct compression or dry granulation.
47. (Original) The composition of claim 44, wherein the composition contains less than 7.5% water.
48. Canceled.
49. (Original) The composition of claim 44, wherein the magnesium salt is the only component present in a therapeutically effective amount.
50. Canceled.
51. Canceled.
52. (Currently amended) A rapidly disintegrating and rapidly dissolving solid oral compressed composition ~~comprising~~ consisting essentially of:
- a. one or more magnesium salts selected from the group consisting of MgO, Mg(OH)₂, MgF₂, and Mg Carbonate;
 - b. ~~one or more hydrophilic polymers, wherein the one or more hydrophilic polymers is a~~ combination of the hydrophilic polymers polyethylene glycol and poloxamer;

- c. one or more disintegrants selected from the group consisting of crospovidone, low substituted hydroxypropylcellulose, croscarmellose sodium, and sodium starch glycolate; and
 - d. at least one or more of the following: surfactant, glidant, filler, and lubricant; wherein
 - e. the composition provides a substantially stable dissolution profile when evaluated in vitro according to USP <711> for the one or more magnesium salts when the composition is stored for at least two months at 40°C and 75% relative humidity in a sealed container-enclosure system;
 - f. the composition is prepared by a substantially anhydrous process;
 - g. the magnesium salt is a sparingly soluble, slightly soluble, very slightly soluble, practically insoluble or insoluble salt;
 - h. the magnesium salt is the only component present in a therapeutically effective amount; and the composition excludes microcrystalline cellulose ~~and erythritol~~.
53. (Original) The composition of claim 52, wherein the composition is prepared by direct compression or dry granulation.
54. (Original) The composition of claim 52, wherein the composition contains less than 7.5% water.
55. Canceled.
56. Canceled.
57. Canceled.
58. Canceled.
59. (New) The composition of claim 1, wherein the composition possesses a disintegration time of 9 to 90 seconds according to USP <701>.
60. (New) The composition of claim 59, wherein the one or more surfactants is present, the one or more glidants is present, the one or more fillers is present, and the one or more lubricants is present.
61. (New) The composition of claim 60 further comprising ethylcellulose and optionally lactose.
62. (New) The dosage form of claim 23, wherein the dosage form possesses a disintegration time of 9 to 90 seconds according to USP <701>.

63. (New) The solid oral dosage form of claim 62, wherein the one or more surfactants is present, the one or more glidants is present, the one or more fillers is present, and the one or more lubricants is present.
64. (New) The solid oral dosage form of claim 63 further comprising ethylcellulose and optionally lactose.
65. (New) The composition of claim 36, wherein the composition possesses a disintegration time of 9 to 90 seconds according to USP <701>.
66. (New) The composition of claim 65, wherein the one or more surfactants is present, the one or more glidants is present, the one or more fillers is present, and the one or more lubricants is present.
67. (New) The composition of claim 66 further comprising ethylcellulose and optionally lactose.
68. (New) The composition of claim 44, wherein the composition possesses a disintegration time of 9 to 90 seconds according to USP <701>.
69. (New) The composition of claim 68, wherein the one or more surfactants is present, the one or more glidants is present, the one or more fillers is present, and the one or more lubricants is present.
70. (New) The composition of claim 69 further comprising ethylcellulose and optionally lactose.
71. (New) The composition of claim 52, wherein the composition possesses a disintegration time of 9 to 90 seconds according to USP <701>.
72. (New) The composition of claim 71, wherein the one or more surfactants is present, the one or more glidants is present, the one or more fillers is present, and the one or more lubricants is present.
73. (New) The composition of claim 72 further comprising ethylcellulose and optionally lactose.
74. (New) A rapidly disintegrating and rapidly dissolving solid oral compressed composition consisting essentially of:
- a. a magnesium salt which is granular MgO;
 - b. a combination of the hydrophilic polymers polyethylene glycol and poloxamer;
 - c. crospovidone;
 - d. one or more surfactants,
 - e. one or more glidants;
 - f. ethylcellulose;

- g. optionally lactose; and
 - h. one or more lubricants; wherein
 - i. the composition provides a substantially stable dissolution profile when evaluated in vitro according to USP <711> for the one or more magnesium salts when the composition is stored for at least two months at 40°C and 75% relative humidity in a sealed container-enclosure system;
 - j. the composition is prepared by a substantially anhydrous process;
 - k. the magnesium salt is a sparingly soluble, slightly soluble, very slightly soluble, practically insoluble or insoluble salt;
 - l. the magnesium salt is the only component present in a therapeutically effective amount; and
 - m. the composition excludes microcrystalline cellulose.
75. (New) The composition of claim 74, wherein the composition possesses a disintegration time of 9 to 90 seconds according to USP <701>.
76. (New) The composition of claim 75, wherein the polyethylene glycol is polyethylene glycol having a molecular weight of 3000-8000, and the poloxamer is poloxamer 188.